

CLAIMS

What is claimed is:

- 1 1. A method of treatment for a mammal in, or at risk of, chronic renal failure
2 comprising
3 administering to said mammal a therapeutically effective amount of an
4 OP/BMP renal therapeutic agent.
- 1 2. A method of treatment to delay the need for, or reduce the frequency of,
2 chronic dialysis treatments comprising
3 administering to a mammal a therapeutically effective amount of an
4 OP/BMP renal therapeutic agent.
- 1 3. A method as in claim 1 wherein said renal therapeutic agent comprises a
2 polypeptide consisting of at least a C-terminal cysteine domain of a protein
3 selected from the group consisting of a pro form, a mature form, and a soluble
4 form of a polypeptide selected from the group consisting of OP-1, OP-2, OP-3,
5 BMP2, BMP3, BMP4, BMP5, BMP6, and BMP9.
- 1 4. A method as in claim 3 wherein said renal therapeutic agent comprises a
2 polypeptide consisting of at least a C-terminal cysteine domain of a protein
3 selected from the group consisting of a pro form, a mature form, and a soluble
4 form of human OP-1.
- 1 5. A method as in claim 1 wherein said renal therapeutic agent comprises a
2 polypeptide having at least 70% homology with an amino acid sequence of a C-
3 terminal seven-cysteine domain of human OP-1.
- 1 6. A method as in claim 5 wherein said polypeptide has at least 75%
2 homology with an amino acid sequence of a C-terminal seven-cysteine domain of
3 human OP-1.

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- 1 7. A method as in claim 5 wherein said polypeptide has at least 80%
2 homology with an amino acid sequence of a C-terminal seven-cysteine domain of
3 human OP-1.
- 1 8. A method as in claim 5 wherein said polypeptide has at least 60% identity
2 with an amino acid sequence of a C-terminal seven-cysteine domain of human OP-
3 1.
- 1 9. A method as in claim 5 wherein said polypeptide has at least 65% identity
2 with an amino acid sequence of a C-terminal seven-cysteine domain of human OP-
3 1.
- 1 10. A method as in claim 5 wherein said polypeptide has at least 70% identity
2 with an amino acid sequence of a C-terminal seven-cysteine domain of human OP-
3 1.
- 1 11. A method as in any one of claims 3-10 wherein said renal therapeutic agent
2 (a) induces chondrogenesis in an ectopic bone assay;
3 (b) prevents, inhibits, delays or alleviates loss of renal function in an animal
4 model of chronic renal failure; or
5 (c) causes a clinically significant improvement in a standard marker of renal
6 function when administered to a mammal in, or at risk of, chronic renal failure.
- 1 12. A method as in claim 1 wherein said renal therapeutic agent is selected
2 from the group consisting of human osteogenic proteins and human bone
3 morphogenetic proteins.
- 1 13. A method as in any one of claims 1-12 wherein
2 said mammal is afflicted with a condition selected from the group
3 consisting of chronic renal failure, end-stage renal disease, chronic diabetic
4 nephropathy, diabetic glomerulopathy, diabetic renal hypertrophy, hypertensive

5 nephrosclerosis, hypertensive glomerulosclerosis, chronic glomerulonephritis,
6 hereditary nephritis, and renal dysplasia.

1 14. A method as in any one of claims 1-12 wherein
2 examination of a renal biopsy of said mammal indicates that said mammal is
3 afflicted with a condition selected from the group consisting of glomerular
4 hypertrophy, tubular hypertrophy, glomerulosclerosis, and tubulointerstitial
5 sclerosis.

1 15. A method as in any one of claims 1-12 wherein
2 examination of said mammal indicates renal fibrosis.

1 16. A method as in claim 15 wherein
2 said examination is an ultrasound, MRI or CAT scan of said mammal.

1 17. A method as in any one of claims 1-12 wherein
2 said mammal possesses a number of functional nephron units which is less
3 than about 50% of a number of functional nephron units present in a mammal
4 having intact healthy kidneys.

1 18. A method as in any one of claims 1-12 wherein
2 said mammal possesses a number of functional nephron units which is less
3 than about 40% of a number of functional nephron units present in a mammal
4 having intact healthy kidneys.

1 19. A method as in any one of claims 1-12 wherein
2 said mammal possesses a number of functional nephron units which is less
3 than about 30% of a number of functional nephron units present in a mammal
4 having intact healthy kidneys.

1 20. A method as in any one of claims 1-12 wherein

2 said mammal possesses a number of functional nephron units which is less
3 than about 20% of a number of functional nephron units present in a mammal
4 having intact healthy kidneys.

1 21. A method as in any one of claims 1-12 wherein
2 said mammal is a kidney transplant recipient.

1 22. A method as in any one of claims 1-12 wherein
2 said mammal possesses only one kidney.

1 23. A method as in any one of claims 1-12 wherein
2 examination of a urinary sediment of said mammal indicates a presence of
3 broad casts.

1 24. A method as in any one of claims 1-12 wherein
2 said mammal has a GFR which is chronically less than about 50% of a
3 GFR_{exp} for said mammal.

1 25. A method as in claim 24 wherein
2 said mammal has a GFR which is chronically less than about 40% of a
3 GFR_{exp} for said mammal.

1 26. A method as in claim 24 wherein
2 said mammal has a GFR which is chronically less than about 30% of a
3 GFR_{exp} for said mammal.

1 27. A method as in claim 24 wherein
2 said mammal has a GFR which is chronically less than about 20% of a
3 GFR_{exp} for said mammal.

1 28. A method as in any one of claims 1-12 wherein
2 said mammal is a human male weighing at least about 50 kg and has a GFR
3 which is chronically less than about 50 ml/min.

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- 1 29. A method as in claim 28 wherein
2 said mammal is a human male weighing at least about 50 kg and has a GFR
3 which is chronically less than about 40 ml/min.
- 1 30. A method as in claim 28 wherein
2 said mammal is a human male weighing at least about 50 kg and has a GFR
3 which is chronically less than about 30 ml/min.
- 1 31. A method as in claim 28 wherein
2 said mammal is a human male weighing at least about 50 kg and has a GFR
3 which is chronically less than about 20 ml/min.
- 1 32. A method as in any one of claims 1-12 wherein
2 said mammal is a human female weighing at least about 40 kg and has a
3 GFR which is chronically less than about 40 ml/min.
- 1 33. A method as in claim 32 wherein
2 said mammal is a human female weighing at least about 40 kg and has a
3 GFR which is chronically less than about 30 ml/min.
- 1 34. A method as in claim 32 wherein
2 said mammal is a human female weighing at least about 40 kg and has a
3 GFR which is chronically less than about 20 ml/min.
- 1 35. A method as in claim 32 wherein
2 said mammal is a human female weighing at least about 40 kg and has a
3 GFR which is chronically less than about 10 ml/min.
- 1 36. A method as in any one of claims 1-12 wherein said treatment reduces
2 serum creatinine levels in said mammal by at least about 5% over 3 months.
- 1 37. A method as in any one of claims 1-12 wherein

2 prior to said treatment said mammal presented a chronic decline in a
3 clinical indicator of renal function; and

4 after at least about 3 months of said treatment, said indicator stabilizes.

1 38. A method as in any one of claims 1-12 wherein said administration is oral.

1 39. A method as in any one of claims 1-12 wherein said administration is
2 parenteral.

1 40. A method as in claim 39 wherein said administration is intravenous.

1 41. A method as in claim 39 wherein said administration is intraperitoneal.

1 42. A method as in claim 39 wherein said administration is into the renal
2 capsule.

1 43. A method as in claim 39 wherein a stent has been implanted into said
2 mammal for said administration.

1 44. A method as in claim 43 wherein said stent is an intravenous stent.

1 45. A method as in claim 43 wherein said stent is an intraperitoneal stent.

1 46. A method as in claim 43 wherein said stent is a renal intracapsular stent.

1 47. A method as in claim 39 wherein said administration is by an implanted
2 device.

1 48. A method as in any one of claims 1-12 wherein said administration is at
2 least once a week for a period of at least about one month.

1 49. A method as in any one of claims 1-12 wherein said administration is at
2 least once a month for a period of at least about one year.

- 1 50. A method as in any one of claims 1-12 wherein said renal therapeutic agent
2 is administered at a dosage of about 0.01-1200 $\mu\text{g/kg}$ body weight of said
3 mammal.
- 1 51. A method as in claim 50 wherein said renal therapeutic agent is
2 administered at a dosage of about 10-300 $\mu\text{g/kg}$ body weight of said mammal.

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